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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/389,000	08/31/99	AFAR	D 1703-018.US1

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GATES & COOPER
HOWARD HUGHES CENTER
6701 CENTER DRIVE WEST, SUITE 1050
LOS ANGELES CA 90045

EXAMINER	
DAVIS,M	
ART UNIT	**PAPER NUMBER**
1642	8

DATE MAILED: 12/05/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/289,000	
Examiner	Group Art Unit
	1641

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication .
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

☒ Responsive to communication(s) filed on 08/15/00.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

☒ Claim(s) 1-53 is/are pending in the application.

Of the above claim(s)_____ is/are withdrawn from consideration.

☐ Claim(s)_____ is/are allowed.

☐ Claim(s)_____ is/are rejected.

☐ Claim(s)_____ is/are objected to.

☒ Claim(s) 1-53 are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The proposed drawing correction, filed on_____ is ☐ approved ☐ disapproved.

☐ The drawing(s) filed on_____ is/are objected to by the Examiner.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 11 9(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number)_____.

☐ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

*Certified copies not received:_____.

Attachment(s)

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s)._____

☐ Interview Summary, PTO-413

☐ Notice of Reference(s) Cited, PTO-892

☐ Notice of Informal Patent Application, PTO-152

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Other_____

Office Action Summary

DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-4, 13, 51, 52 drawn to Phelix protein, classified in class 530, subclass 350.

II. Claims 5-12, drawn to an isolated polynucleotide encoding Phelix protein, an expression vector containing said polynucleotide, a host cell containing said vector, and a process for producing a Phelix protein classified in class 536, subclass 23.1.

III. Claims 14-22, 24, 28, drawn to an antibody which specifically binds to Phelix protein, fragments thereof, a hybridoma producing said antibody, a humanized antibody, a human antibody, and a single chain antibody classified in class 530, subclass 387.1.

IV. Claim 23, drawn to a transgenic animal producing said human antibody, classified in class 800, subclass 2.

V. Claims 25-27, drawn to a recombinant protein comprising the antigen binding region of said antibody, classified in class 530, subclass 387.1.

VI. Claim 29, drawn to a vector comprising a polynucleotide encoding said single chain antibody, classified in class 536, subclass 23.53.

VII. Claim 30, drawn to a method for detecting the presence of a Phelix protein, using an antibody specific for Phelix protein, or fragment thereof, or a recombinant protein comprising the antigen binding region of said antibody classified in class 435, subclass 7.1.

VIII. Claim 31, drawn to an assay for detecting the presence of a Phelix polynucleotide, using hybridization probes, classified in class 435, subclass 6.

IX. Claim 32, drawn to an assay for detecting the presence of a Phelix polynucleotide, using reverse transcription, classified in class 435, subclass 91.1.

X. Claims 33, 39-43, drawn to a method for diagnosis of cancer by detecting the level of Phelix protein, classified in class 435, subclass 7.1.

XI. Claims 34-38, drawn to a method for diagnosis of cancer by detecting the level of Phelix mRNA, classified in class 435, subclass 6.

XII. Claims 44-45, drawn to a method of treating cancer, using single chain antibody specific for Phelix protein, classified in class 424, subclass 130.1.

XIII. Claims 46-47, drawn to a method of treating cancer, by inhibiting transcription of Phelix, classified in class 514, subclass 44.

XIV. Claims 48-49, drawn to a method of treating cancer, by inhibiting translation of Phelix using an antisense polynucleotide, classified in class 514, subclass 44.

XV. Claims 48, 50, drawn to a method of treating cancer, by inhibiting translation of Phelix using a ribozyme, classified in class 514, subclass 2.

XVI. Claim 50, drawn to a method for inhibiting development of cancer, by administering a vaccine comprising a Phelix protein, classified in class 514, subclass 2.

In addition, upon the election of group II, further election of the following patentably distinct species of the claimed invention is required:

1) SEQ ID NO:1,

2) SEQ ID NO:1, where T can be U, or

3) residue number 735 through 1949 of SEQ ID NO:1, where T can be U.

Upon the election of group III, further election of the following patentably distinct species of the claimed invention is required:

An antibody and its fragment, a humanized antibody, a human antibody, or a single chain antibody.

Radioisotope, fluorescent compound, bioluminescent compound, chemiluminescent compound, metal chelator, or enzyme.

Upon the election of group VII, further election of the following patentably distinct species of the claimed invention is required:

An antibody, or a recombinant protein comprising the antibody binding region of an antibody.

Upon the election of any of groups X-XVI, further election of the following patentably distinct species of the claimed invention is required:

Prostate cancer, bladder cancer, ovary cancer or testicular cancer.

2. The inventions are distinct, each from the other because of the following reasons:

Inventions (I-VI) and (VII-XVI) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. 806.05 (h). In this instant case, a polypeptide could be used for several purposes, e.g. for biochemical assay, for making antibodies, and for making an affinity column to purify its antibodies; a DNA sequence could be used for the detection of similar DNA or RNA sequences, for making an expression vector, and for producing its encoded protein; and an antibody could be used for immunoassay, for purification of its antigen, and for detection of diseases.

The products of groups I-VI are patentably distinct, because they are drawn to entirely different biochemicals or animal, having different structures, biological properties and activities that are not interchangeable and/or cannot be used in place of each other or together.

The methods of groups VII-XVI differ in the method objectives, method steps and parameters and in the reagents used.

The species polynucleotides are distinct from each other, because they are structurally distinct, or having different properties.

The species antibody are distinct from each other, because they are structurally distinct.

The species detectable markers are distinct from each other, because they are structurally distinct.

The species cancer are distinct from each other because each type of cancer has different characteristics, and etiology.

Because these inventions are distinct for the reason given above and have acquired a separate status in the art as shown by their different classification, and because the searches for the groups are not co-extensive, restriction for examination purposes as indicated is proper.

Applicants are required under 35 USC 121 to elect a single disclosed group for prosecution on the merits to which the claims shall be restricted. Applicant is further advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the

examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 USC 103 of the other invention.

Applicants are reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendement of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. 1.48(b) and by the fee required under 37 C.F.R. 1.17(h).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Minh-Tam B. Davis whose telephone number is (703) 305-2008. The examiner can normally be reached on Monday-Friday from 9:30am to 3:30pm, except on Wesnesday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tony Caputa, can be reached on (703) 308-3995. The fax phone number for this Group is (703) 308-4227.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0916.

Minh-Tam B. Davis

SUSAN UNGAR, PH.D
PRIMARY EXAMINER

November 28, 2000